PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

Translation

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 1559	Date of mailing *(day/month/year)* FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/005115	09.04.2004	11.04.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant
KYOWA HAKKO KOGYO CO. LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.
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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 18-22

because:

☒ the said international application, or the said claims Nos. 18-22 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matters of claims 18-22 relate to a method for treatment of the human body.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 18-22

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5, 11, 17	YES
	Claims	1-4, 6-10, 12-16, 23-27	NO
Inventive step (IS)	Claims		YES
	Claims	1-17, 23-27	NO
Industrial applicability (IA)	Claims	1-17, 23-27	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP, 2001-78667, A (Fuso Chemical Co., Ltd.), 27 March, 2001 (27.03.01)(Family: none)
Document 2: Nippon Nogei Gakkai Koen Yoshishu, 5 March, 2003 (05.03.03), Vol. 20003, p. 58
Document 3: JP, 9-503197, A (Nutramax laboratories, Inc.), 31 March, 1994 (31.03.94)
Document 4: JP, 2003-81838, A (Rohto Pharmaceutical Co., Ltd.), 19 March, 2003 (19.03.03)(Family: none)
Document 5: Journal of Traditional medicines, 1998, Vol. 15, No. 5, pp. 296-297
Document 6: JP, 2001-72582, A (Sunstar Inc.), 21 March, 2001 (21.03.01)(Family: none)
Document 7: JP, 2003-501381, A (University of Sheffield), 14 January, 2003 (14.01.03)

The above documents 1-7 are cited in the ISR.

The subject matters of claims 1-5, 7-10, 12-16 and 23-27 do not appear to be novel, since document 1 describes a remedy for arthritis or a health drink which are obtained by combining glucosamine and tea, and also describes Hydrangea tea can be used as the tea.

Document 2 describes Hydrangea tea has an effect of controlling of TNF-α yield and that of preventing arthritis. Documents 3 and 4 describe that glucosamine and chondroitin sulfuric acid are used as a remedy for arthritis. Document 5 describes Thunberginol, which is polyphenol of Hydrangea tea, has an immunosuppressive effect. Document 6 describes a synergistic remedy for arthritis obtained by combining polyphenol and glucosamine, and document 7 describes a synergistic remedy for arthritis obtained by combining catechol, which is polyphenol having an effect of controlling of TNF-α yield, and glucosamine or glucosamine sulfuric acid. On the other hand, Hydrangea tea is a well-known additive for foods or drinks as sweetening before this application. So, it is considered to be obvious for a person skilled in the art that Hydrangea tea and glucosamine or chondroitin sulfuric acid, which are respectively known for their having an effect of treating arthritis, are combined to constitute a more effective remedy for arthritis. And it is also considered to be obvious for a person skilled in the art that the polyphenol components or the components of Hydragea tea as an inhibitor of TNF-α yield described in documents 6 and 7 are adopted in order to provide a remedy for arthritis, foods and drinks, an additive for foods and drinks, livestock feed or an additive for livestock feed.

Therefore, the subject matters 1-17 and 23-27 do not appear to involve an inventive step.